

DEPARTMENT OF HEALTH & HUMAN SERVICES

MAR 2 5 2004

FAP 2234 Natamycin

Arkion Life Sciences c/o Franklin Carter 1082 Duna Drive Laramie, Wyoming 82072 BASIL KAKELIS

178 3600

Food and Drug Administration

Rockville MD 20857

DEGE | VE | APR 0 5 2004

Dear Mr. Carter:

We refer to your Food Additive Petition of July 31, 2001, in which you requested that Title 21, Part 573 of the Code of Federal Regulations (21 CFR 573) be amended to provide for the safe use of natamycin in broiler chicken feeds. Natamycin would be added to broiler chicken feed at a level of 11 parts per million to retard the growth of Aspergillus parasiticus in the feed for up to 14 days after addition of natamycin to the feed.

The petition is an amendment to an earlier one in which you attempted to establish the safety and utility of natamycin when used in broiler chicken feeds to retard the growth of Aspergillus parasiticus, Penicillium rubrum, and Fusarium moniliforme. We filed that original petition for you on September 6, 1995.

We have completed our review of your amended petition, and find that the data adequately support the safety and functionality of natamycin for the intended use. The petition will be approved when the final rule is published in the Federal Register.

Please feel free to contact Dr. Sharon Benz, Acting Director of our Division of Animal Feeds, at 301-827-6656, if you have any questions about the contents of this letter.

Sincerely yours.

Stephen F. Sundlof, DVM, Ph.D.

Director, Center for Veterinary Medicine